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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,452

06/03/2005

Luca Barella

DSM-01-US

3265

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7590

02/12/2009

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EXAMINER

WINSTON, RANDALL O

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/537,452		BARELLA ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Randall Winston		1655	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1108</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/2008 has been entered.

Claims 25-37 have been examined on the merits.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-37 are also rejected under 35 USC 112, first paragraph, because the specification, while enabling for a method of incidence risk reduction of non-cancerous symptoms or pathologies associate with androgen signaling of polycystic ovary syndrome comprising administering an effective amount of lycopene, the specification does not enable any person in the art in preparing a method of incidence risk reduction of any and/or all non-cancerous symptoms or pathologies associate with androgen comprising administering an effective amount of lycopene; nor does the specification enable any person in the art to prepare a method of prophylactic (i.e. to prevent) nutritional supplementation of healthy subjects to reduce the risk reduction of non-

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cancerous symptoms or pathologies associate with androgen comprising administering an effective amount of lycopene. The specification does not enable any person skilled in the art to which it pertains, or with which is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a method of incidence risk reduction of any and/or all non-cancerous symptoms or pathologies associate with androgen comprising administering an effective amount of lycopene. Applicant has reasonably demonstrated in example 2 on page 14 of the specification, a method of incidence risk reduction of non-cancerous symptoms or pathologies associate with androgen signaling of polycystic ovary syndrome comprising administering an effective amount of lycopene. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method of incidence risk reduction of any and/or all non-cancerous symptoms or pathologies associate with androgen comprising administering an effective amount of lycopene. Moreover, applicant claims a method of prophylactic (i.e. to prevent) nutritional supplementation of healthy subjects to reduce the risk reduction of

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non-cancerous symptoms or pathologies associate with androgen comprising administering an effective amount of lycopene. Please note the term prevent (i.e. a prophylactic) is an absolute definition which means to stop occurring and, as such, requires a higher standard for enablement than the instantly disclosed invention. Applicant has reasonably demonstrated in example 2 on page 14 of the specification, a method of incidence risk reduction of non-cancerous symptoms or pathologies associate with androgen signaling of polycystic ovary syndrome comprising administering an effective amount of lycopene. Applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method of prophylactic (i.e. to prevent) nutritional supplementation of healthy subjects to reduce the risk reduction of non-cancerous symptoms or pathologies associate with androgen comprising administering an effective amount of lycopene. Accordingly, it will take undue experimentation without reasonable expectation of success for one skill in the art to prepare a method of prophylactic (i.e. to prevent) nutritional supplementation of healthy subjects to reduce the risk reduction of non-cancerous symptoms or pathologies associate with androgen comprising administering an effective amount of lycopene.

Furthermore, it should be noted that the state of the prior art at the time the invention was filed did not recognize a method of incidence risk reduction of any and/or all non-cancerous symptoms or pathologies associate with androgen comprising administering an effective amount of lycopene. For example, Lorant et al. teach (see, e.g. US 6,623,769) an effective amount of lycopene is administered to a subject in need

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thereof to treat pathologies associated with androgen signaling such as acne. Thus, the art is silent regarding the efficacy of applicant's method of incidence risk reduction of any and/or all non-cancerous symptoms or pathologies associate with androgen comprising administering an effective amount of lycopene. Therefore, applicant's claimed method of incidence risk reduction of any and/or all non-cancerous symptoms or pathologies associate with androgen comprising administering an effective amount of lycopene is unpredictable in the art. In addition, applicant's specification, however, has failed to provide guidance or working examples whereby applicant prepares a method of incidence risk reduction of any and/or all non-cancerous symptoms or pathologies associate with androgen comprising administering an effective amount of lycopene.

Therefore, it would require undue experimentation without a reasonable expectation of success for one of skill in the art to practice the invention commensurate in scope with the claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-37 are stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lorant et al. (US 6623769) in view of Murad (US 5962517) and De Salvert (US 5827520).

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Applicant claims a method of prevention (i.e. prophylactic) and/or incidence risk reduction of any and/or all non-cancerous symptoms or pathologies associate with androgen comprising administering an effective amount of lycopene and further comprising vitamin e and vitamin c whereas the claimed active ingredients of lycopene, vitamin e and vitamin c are administered in various amounts.

Lorant teaches an effective amount of lycopene is orally administered to a subject in need thereof to treat pathologies associated with androgen signaling such as acne. Moreover, when Lorant same lycopene as the claimed invention's lycopene is orally administered in effective amounts within a subject in need of's body to treat acne, Lorant's same lycopene as the claimed invention's lycopene would also inherently have the same underlining claimed functional effect as the claimed invention when administered to a subject in need thereof (i.e. the functional effect of incidence risk reduction of androgen signaling of pathologies associated with androgen signaling such as acne- i.e. also please note that Applicant also readily admits within his specification on page 7 lines 27-29 that acne is a pathology associated with androgen signaling) (also please note since applicant is also claiming the use of lycopene as a prophylactic, the administered of lycopene as a prophylactic to a subject in need thereof would read on treating or preventing any and/or all diseases instead of only treating or preventing the claimed pathologies associated with androgen signaling) (see, e.g. entire patent including column 3 lines 5-10 and page 7 lines 27-29). Lorant does not expressly teach the combination of lycopene, vitamin e and vitamin c administered to a subject in thereof to treat pathologies associated with androgen signaling such as acne.

Murad beneficially teaches vitamin e treats pathologies associated with androgen signaling such as acne (see, e.g. entire patent including column 3 lines 1-10).

De Salvert beneficially teaches vitamin c treats pathologies associated with androgen signaling such as acne (see, e.g. entire patent including column 4 lines 50-55).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Lorant to include the claimed active ingredients of vitamin e and vitamin c as taught by Murad and De Salvert within Lorant's method teachings because the above combined reference as a whole would create the claimed invention of a method of prevention (i.e. prophylactic) and/or incidence risk reduction of non-cancerous symptoms or pathologies associate with androgen which comprises administering to a subject in need of an effective amount of the combination of lycopene, vitamin e and vitamin c. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (i.e. to treat acne), in order to form a third composition to be used for the same purpose" Furthermore, the adjustment of other conventional working conditions (e.g. determining suitable amounts/ranges of each active ingredient within the claimed composition and the amounts and times per day the claimed composition's method is administered), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

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Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant's argument has been carefully considered but it is not deemed persuasive. Applicant argues claims 25-31 are not obvious over Lorant in view of De Salvert. Neither reference teaches or suggests incidence risk reduction of pathologies associated with androgen signaling in patients at elevated risk for such pathologies, by administering an effective amount of lycopene to reduce androgen signaling.

Although Applicant argues neither reference teaches or suggests incidence risk reduction of pathologies associated with androgen signaling in patients at elevated risk for such pathologies, by administering an effective amount of lycopene to reduce androgen signaling, Applicant argument is not found persuasive because Lorant teaches an effective amount of lycopene is administered to a subject in need thereof to treat pathologies associated with androgen signaling such as acne. Lorant does not expressly teach the combination of lycopene and vitamin c administered to a subject in need thereof to treat pathologies associated with androgen signaling such as acne. However, De Salvert is referenced by examiner to remedy Lorant's deficiency. De Salvert beneficially teaches vitamin c treats pathologies associated with androgen signaling such as acne. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Lorant to include the

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claimed active ingredient of vitamin c as taught by De Salvert within Lorant's method teachings because the above combined reference would create the claimed invention of a method of treatment of symptoms or pathologies associated with androgen signaling such as acne which comprises administering to a subject in need of such treatment for therapy an effective amount of the combination of lycopene and vitamin c. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (i.e. to treat acne), in order to form a third composition to be used for the same purpose" Furthermore, the adjustment of other conventional working conditions (e.g. determining suitable amounts/ranges of each active ingredient within the claimed composition and the amounts and times per day the claimed composition's method is administered), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655